

**WHEREAS**, the public interest in full and open disclosure of judicial process under Article III of the United States Constitution will not be significantly thwarted by maintaining the confidentiality of this information.

**THEREFORE, IT IS HEREBY STIPULATED AND AGREED**, by and between the attorneys for Plaintiffs and Defendants, and the Court enters this Protective Order under Fed. R. Civ. P. 26(c) and hereby **ORDERS** that documents and other information produced in this case by the parties shall be produced subject to the following:

**1. SCOPE**

A. At any time before the production of any documents or information by the Producing Party, if warranted under applicable law, the Producing Party may designate such information or documents as Confidential and subject to this Protective Order. The Court anticipates that before designating documents Confidential pursuant to this Confidentiality Order, the Producing Party shall make a good faith analysis of its document production to determine if such documents merit confidential treatment under applicable law. This Protective Order does not confer blanket protection to all disclosures, documents, or responses to discovery, and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal protections for treatment as confidential. The Producing Party shall designate those materials as Confidential and subject to this Protective Order by placing the following legend or similar marking on each page of each document copied for, by, or on behalf of the plaintiff or co-defendants in this action: **“CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER.”** The legend shall be placed in a manner which will not in any way interfere with or obliterate its legibility. Documents or information so designated shall be referred to herein as “Confidential Discovery Material.” Such stamping or marking will take place before production by the Producing Party or subsequent to selection by the Receiving Party for copying.

B. With the exception of documents or information that have become publicly available without breach of the terms of this Order or any other legal obligation to safeguard and

maintain confidentiality, all documents, information or other discovery materials produced or discovered in this litigation, and that have been designated as “Confidential Discovery Materials” shall be used by the Receiving Party solely for the prosecution or defense of this litigation.

C. “Confidential Discovery Material” as used herein means any non-public information, document (electronic or hardcopy), or tangible thing, response to discovery requests, deposition testimony or transcript, and any other similar materials, or portions thereof that are properly protected under Fed. R. Civ. P. 26(c) or other applicable law. Confidential Discovery Material includes information which, if disclosed to a competitor, could result in substantial business harm by revealing current proprietary licensing, marketing, design, development, research, manufacturing or business strategy information regarding products or medicines relating to this lawsuit. Nothing herein shall be construed to allow for global designations of all documents as “Confidential.”

D. This Protective Order shall apply to and govern all hard copy and electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, disks, networks, or tapes) (Electronically Stored Information (“ESI”)), the information contained therein, and all other information produced or disclosed and designated by the Producing Party as Confidential whether or not such documents or information are informally produced or produced in response to formal discovery requests. The Producing Party may designate specific answers to interrogatories, responses to other discovery requests, and excerpts of deposition testimony as Confidential pursuant to this Protective Order. When ESI is produced by a party in such form and contains Confidential Discovery Material, the Producing Party shall so indicate by labeling

the media as follows: "Contains Confidential Material." If appropriate, individual documents or pages contained on the media shall be marked in the manner set forth in paragraph 1(A) above.

E. This Protective Order is binding upon all parties at the time this Protective Order is entered, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Protective Order. If additional parties are added other than parents, subsidiaries and affiliates of current parties to this litigation, their ability to receive Confidential Discovery Material as set forth in this Protective Order will be subject to them being bound, by agreement, or Court Order, to this Protective Order.

F. The entry of this Protective Order does not preclude any party from seeking such further provisions enhancing or limiting confidentiality as may be appropriate.

G. With respect to deposition testimony, a designation of confidentiality may be made on the record at the time of a deposition, at which time the testimony and transcript thereof shall be subject to the full protection of this Protective Order. However, within thirty (30) days after receipt of the final deposition transcript from the court reporter, counsel for the party asserting confidentiality at the deposition shall state in writing, served on all parties, by designating the pages and lines of all portions for which confidentiality is claimed. In the case of testimony not so designated during the course of a deposition, counsel for the party wishing to assert confidentiality may, at any time within thirty (30) days of receipt of the final deposition transcript from the court reporter, notify the parties and court reporter in writing, by designating by pages and lines of all portions for which confidentiality is claimed, in which case those portions of the testimony and transcript thereof shall be subject to the full protection of this Protective Order. During the thirty (30) day period, the testimony will be treated as though it

had been designated as confidential pursuant to the terms of this Protective Order. If the Producing Party does not serve a designation letter within the thirty (30) day period, then the entire transcript will be deemed not to contain any Confidential Information.

H. Nothing herein shall be construed to affect in any manner the admissibility at trial or in any other Court proceeding of any document, testimony or other evidence. Use of Confidential Discovery Material subject to this Protective Order at trial will be determined by relevant law and order of the Court.

## **2. FILING OF CONFIDENTIAL INFORMATION WITH THE COURT**

If a party intends to file a document containing Confidential Information with the Court, this Protective Order grants leave to make such filing under seal in compliance with Local Rule 5.3 and/or the Electronic Case Filing/Case Management procedures manual. Prior to disclosure at trial or a hearing of Confidential Discovery Material the parties may seek further protections against public disclosure from the Court.

## **3. REDACTIONS**

A. To protect against unauthorized disclosure of Confidential Discovery Material, and to comply with all applicable state and federal laws and regulations, the Producing Party may redact from produced documents, materials and other things, the following items, or any other item(s) protected from disclosure by statute or decisional authority or agreed upon by the parties or ordered by the Court:

1. The names, street addresses, Social Security numbers, tax identification numbers, and other personal identifying information of patients, health care providers, and individuals in clinical studies or adverse event reports. Other general identifying information, however, such as patient or health provider numbers, shall not be redacted unless required by state or federal law. To the extent a plaintiff's name is contained in any of these documents, a

copy of the documents that have not had the plaintiff's information redacted will be produced directly to counsel for said plaintiff.

2. The Social Security numbers, tax identification numbers and other personal identifying information of employees in any records.

B. Defendants reserve the right to redact information that is nonresponsive (including proprietary financial material unrelated to this litigation). Defendants will consult with Plaintiffs concerning any such redaction prior to producing the redacted document.

C. To the extent that the Producing Party redacts material or information in the produced documents or portions thereof, it shall black out every redaction to indicate where the redaction begins and ends.

D. Every redaction in every document shall be marked as described in paragraph 3(C) above.

E. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as Confidential, regardless of whether the document containing such names is designated as Confidential Information.

F. Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of a party's ability to challenge such redactions and require the Producing Party to seek a protective order nor restrict a party's right to otherwise seek protection from the Court concerning any such request. The parties shall meet and confer before engaging in any motion practice with respect to this paragraph. The burden as to the propriety of any redaction remains on the Producing Party at all times.

#### **4. ACCESS TO AND USE OF CONFIDENTIAL INFORMATION**

A. Except with the prior written consent of the party or other person originally

producing Confidential Discovery Material, or as herein provided under this Order, no Confidential Discovery Material, or portions thereof, may be disclosed to any person except as set forth below.

B. Any person having knowledge of Confidential Discovery Material by virtue of participation in this proceeding, or by virtue of obtaining documents or other Confidential Discovery Material produced or disclosed under this Protective Order, shall use the Confidential Discovery Material only as permitted by this Protective Order. Counsel shall take all reasonable and necessary steps to assure the security of any Confidential Discovery Material and will limit access to Confidential Discovery Material to those persons authorized by this Protective Order.

C. The documents and information provided by the Producing Party and designated as confidential shall be revealed to and used by (1) the parties to this litigation (including partners, directors, officers, and employees of Parties); (2) Counsel to the Parties who have entered appearances in this litigation, members of their firms, associate attorneys, contract attorneys, paralegals, secretarial staff, clerical and other regular or temporary employees, and service vendors of such counsel (including outside copying services and outside litigation support services such as translators and interpreters); (3) independent consultants and/or experts, employed and/or formally retained to advise or to assist counsel in the preparation and/or trial of this litigation; (4) the Court and its respective staff and administrative personnel; Court reporters, stenographers and videographers employed to take depositions; and, any essential personnel retained by the Court; (5) Persons working in connection with this litigation under the direct supervision of persons described above in (1)-(4), but only to the extent necessary to perform their work in connection with this litigation; (6) Persons who authored the Confidential Discovery Material or who received such Confidential Discovery Material in the ordinary course

of business; (7) Persons noticed for depositions or designated as trial witnesses and their attorneys, or those counsel of record who in good faith expect to testify at deposition or trial, to the extent reasonably necessary in preparing to testify; (8) and plaintiffs' treating physicians. The parties agree that the documents designated as Confidential may be revealed to additional persons, including parties and/or in-house counsel, by agreement, which shall not be unreasonably withheld. Under no circumstances shall any of the above eight (8) categories of persons disclose such Confidential Discovery Material to the press or media.

D. Each person as defined in 4(C)(3) and 4(C)(5) through (8) who reviews or inspects Confidential Discovery Material subject to this Protective Order shall be brought within the personal jurisdiction of this Court, including the contempt power, by signing a copy of the attached Acknowledgement signifying agreement to the provisions of this Protective Order and consenting to the jurisdiction of this Court over his/her person for any proceedings involving alleged improper disclosure of said protected documents or information.

**Plaintiffs' Counsel shall not disclose or provide Confidential Discovery Material to any third party who refuses to execute an Acknowledgement. Once Plaintiffs' counsel learns of a third party's refusal to execute an Acknowledgement, counsel shall so notify counsel for the producing party immediately, if the third party has been noticed or otherwise scheduled for deposition.**

**If the third party articulates his/her refusal to execute an Acknowledgement at the scheduled deposition, the third party shall be requested to state on the record the reason(s) for his/her refusal, and affirm, under oath, that s/he will not discuss or disclose to others the content, sum or substance of any Confidential Discovery Material utilized during the deposition. After the witness has so affirmed, Confidential Discovery Material**



**may be shown to the witness during the course of the deposition. Under no circumstance, however, shall Plaintiffs' counsel provide copies of any Confidential Discovery Material to any third party who refuses or has failed to execute an Acknowledgement.**

E. With the exception of persons set forth in 4(C)(1), 4(C)(2) and 4(C)(4) above and 4(F) below, no person entitled to access to Confidential Discovery Material under this Protective Order shall be provided with the protected documents or information unless each such individual has first read the Protective Order of this Court and completed and signed the Acknowledgement attached as Exhibit A. No person entitled to access to protected documents or information shall disclose or discuss the contents of any such materials with any other individual, except those individuals who are also permitted to view, inspect or examine the materials protected herein. The information provided by this Protective Order shall be used for the sole purpose of the preparation for this case, and shall not be used for any other purpose or for any other legal action except as provided by this Protective Order.

F. Persons who come into contact with Confidential Discovery Material for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgements but must comply with the terms of this Order.

G. The signed Acknowledgements are strictly confidential except as stated below.

H. Each party's counsel shall maintain all executed Acknowledgements of all persons who inspect or review confidential documents obtained from another party before trial of this matter or who receives any copies of such Confidential Discovery Material. Each party will produce a copy of the executed Exhibit A for each of its testifying experts along with that expert's report. With the exception of the expert provision discussed in this section, the parties expressly agree, and it is hereby Ordered that except in the event of a violation of this Order, the

parties will make no attempt to seek copies of the signed Acknowledgements or to determine the identities of the persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Order, such disclosure will be made under a separate court order.

I. The terms of this Order do not apply to any publicly available information or documents. This provision in no way alters or expands the terms of paragraph 4(c) of this Protective Order identifying the persons to whom Confidential Discovery Material has been revealed.

J. Nothing herein shall restrict a person qualified to receive Confidential Discovery Material under this Protective Order from making working copies, abstracts, digests, and analyses of such information for use in connection with this proceeding and such working copies, abstracts, digests, and analyses shall be deemed to have the same level of protection under the terms of this Protective Order. A qualified recipient shall at all times keep secure all notes, abstracts, or other work product derived from or containing Confidential Discovery Material, shall be obliged to maintain the confidentiality of such work product, and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other things, or portions thereof (and the information contained therein) and information are returned or destroyed. Nothing in this Protective Order requires the Receiving Party's counsel to disclose work product at the conclusion of this litigation.

K. Any non-party who is producing Discovery Materials in this litigation may agree to and obtain the benefit of the terms and protections of this Order by designating "Confidential" those discovery materials that the non-party is producing which are properly confidential under applicable law.

## **5. APPLICATION TO THE COURT**

A. Nothing herein shall be construed to preclude or limit any party from opposing

any discovery on any ground which would otherwise be available. Nothing in this Protective Order shall be deemed to preclude any party from seeking or obtaining, on the appropriate showing, additional protection with respect to the confidentiality of documents or information. Nothing in this Protective Order shall preclude any party from seeking or obtaining, on the appropriate showing, an order lifting the protection granted in this Protective Order with respect to the confidentiality of documents or information.

B. It shall be the burden of the party seeking to prevent disclosure to demonstrate good cause for prohibiting disclosure.

**6. VIOLATION OF PROTECTIVE ORDER**

A violation by any person of any provision of this Protective Order may be punishable as determined by the Court.

**7. JURISDICTION OF COURT**

This Court retains jurisdiction over the parties, counsel for the parties, and all persons, firms, corporations, or organizations, whomsoever, to whom this Protective Order applies, for purposes of enforcement of this Protective Order both during and following the conclusion of this action.

**8. CHALLENGE TO CONFIDENTIALITY DESIGNATIONS OR REDACTIONS.**

A. If a party elects to challenge any designation or re-designation of the confidentiality of any documents, information or redactions pursuant to this Protective Order, the Receiving Party shall provide the Producing Party written notice of the dispute, specifying by exact Bates number(s) the Confidential Discovery Material in dispute and afford the Producing Party the opportunity to voluntarily remove such designation or redaction. The Producing Party shall, within thirty (30) days of the receipt of such notice, either voluntarily remove the designation or file a written motion with the Court that identifies the challenged material and sets

forth in detail the basis for the confidential designation or redaction. The confidentiality of challenged documents, information, or the legitimacy of any redaction shall remain protected until the Court shall order otherwise. Notification of any such dispute does not in any way suspend the operation of this Order. In the event the Producing Party files a motion seeking protection of challenged documents, information, or redaction, the party opposing the motion shall have ten (10) days to file a response and the Producing Party shall have seven (7) days to file a reply.

B. The interested parties shall attempt to resolve any such challenges by agreement prior to the time for filing of the motion required pursuant to paragraph 8(A). If the challenge is resolved by agreement, or by voluntary removal, or if no motion is filed within thirty (30) days of the receipt of written notice of challenge, then within thirty (30) days of the agreement or of the challenging party's notice of the dispute if there is no agreement, the Producing Party shall remove the Confidential legend or redaction stamp and shall provide documents without the Confidentiality legend or stamp to the Receiving Party and Confidentiality shall not thereafter apply to such documents or information. If the Court orders production of Confidential Discovery Material or redacted material, then the confidential legend or redaction and reason therefore shall be removed by the Producing Party within thirty (30) days of entry of the Court's order and all documents without the confidentiality legend or redaction will be produced to the Receiving Party. Confidentiality shall not thereafter apply to such documents or information.

1. All documents, testimony, or other materials designated by the producing party as confidential shall retain their confidential status during the pendency of any proceeding challenging confidentiality initiated by a party until such time as the contentions initiated by a party regarding confidentiality of documents and materials so designated are fully and finally

adjudicated, including such appeals as may be sought.

2. Neither this Protective Order nor the designation of any item as Confidential Discovery Material shall be construed as an admission that such material or any testimony in respect to such material in a deposition or otherwise would be admissible in evidence in this litigation or in any other proceeding. In addition, this Protective Order does not, of itself, require the production of any information or document.

C. The burdens of both proof and persuasion in any such challenge proceeding shall be on the Producing Party.

**9. THIRD PARTY REQUEST FOR CONFIDENTIAL DISCOVERY MATERIAL**

A. If Confidential Discovery Material in the possession of a receiving party are subpoenaed or requested by any court, administrative or legislative body, or any other person or organization purporting to have authority to subpoena or request such data or information, the party to whom the subpoena or request is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information without waiting ten (10) business days after first notifying counsel for the Producing Party in writing of: (1) the information and documentation which is requested for production in the subpoena or request; (2) the date on which compliance with the subpoena or request is sought; (3) the location at which compliance with the subpoena or request is sought; (4) the identity of the party serving the subpoena or making the request; and (5) the case name, jurisdiction, and index, docket, complaint, charge, civil action, or other identification number or designation identifying the litigation, administrative proceeding, or other proceeding in which the subpoena or request has been issued.

B. Upon receiving a subpoena or request by any court, administrative or legislative body, or any other person or organization purporting to have authority to subpoena or request

such data or information, the original Producing Party shall bear the burden and all costs of opposing production, if it deems it appropriate to do so.

**10. INADVERTENT OR UNINTENTIONAL DISCLOSURE**

A. **Private and Privileged Information.** Pursuant to Federal Rule of Evidence 502(d) and Federal Rule of Civil Procedure 26(b)(5)(B), the production or disclosure of any discovery material made in connection with this action that a party claims was inadvertent and should not have been produced or disclosed based on privacy, attorney-client and/or work-product privilege, or HIPAA (“Inadvertently Produced Material”) will not be deemed to be a waiver in whole or in part of privacy, privilege, HIPAA, or any other protections to which the party would have been entitled had the affected material not inadvertently been disclosed, either as to the specific information and/or documents disclosed or as to any other information and/or documents in this litigation and in any other federal or state proceeding. In the event of a claimed inadvertent disclosure, the following procedures shall be followed:

1. The Producing Party shall notify the Receiving Party in writing within a reasonable period of time from the discovery of the inadvertent production by specifically identifying the affected material;

2. If the Producing Party requests the return of any Inadvertently Produced Material, those to whom the request is made shall return to the Producing Party immediately all copies of the affected material within their possession, custody, or control—including all copies in the possession of experts, consultants, or others to whom the affected material was provided;

3. All notes or other work product of the Receiving Party reflecting the contents of the Inadvertently Produced Material shall be destroyed, and the returned or destroyed material shall be deleted from any litigation-support or other database;

4. If, after being notified of the inadvertent disclosure, the Receiving

Party promptly disputes in writing the claim of privilege, that party must promptly return, sequester, or destroy any copies of the Inadvertently Produced Material in accordance with Federal Rule of Civil Procedure 26(b)(5)(B), as well as any notes or other work product of the Receiving Party reflecting the contents of such materials, and may promptly present the information, including the Inadvertently Produced Material, to the court under seal for a determination of the claim of privilege;

5. Pending resolution of the matter by the court, no use or disclosure shall be made of the Inadvertently Produced Material for any purpose, including, but not limited to, during depositions or at trial;

6. If the court determines that the Inadvertently Produced Material is privileged, the Receiving Party shall promptly comply with the immediately preceding provisions of this paragraph or such other directives as may be issued by the court. If the court determines that the Inadvertently Produced Material is not privileged, the material is to be immediately returned to the Receiving Party; and

7. Where the privilege or privacy at issue may be protected by redacting that information, the Producing Party shall provide redacted discovery material to replace the inadvertently disclosed documents within 5 business days after requesting the return of any such discovery.

**B. Confidential Discovery Materials.** The production or disclosure of any Confidential Discovery Materials that a party claims was inadvertent and should not have been produced or disclosed without a confidentiality designation shall not be deemed a waiver in whole or in part of a subsequent claim of protected treatment, either as to the specific information and/or documents disclosed or as to any other information and/or documents in this

litigation and in any other federal or state proceeding. In the event of a claimed inadvertent disclosure, the following procedures shall be followed:

1. The Producing Party shall notify the Receiving Party in writing within a reasonable period of time from the discovery of the inadvertent production by specifically identifying the affected material;
2. Upon written notice, the Receiving Party shall immediately mark and treat as confidential all copies of the affected material within their possession, custody, or control—including all copies stored in or downloaded from any litigation-support or other database, as well as all copies in the possession of experts, consultants, or others to whom the affected material was provided;
3. If, after being notified of the inadvertent disclosure, the Receiving Party promptly disputes in writing the claim of confidentiality, that party may promptly present the information to the court under seal for a determination of the claim of confidentiality; and
4. Pending resolution of the matter by the court, the Receiving Party shall treat the affected material as Confidential Discovery Material subject to the full protections of this order.

**11. RETURN OR DESTRUCTION OF CONFIDENTIAL DOCUMENTS AND INFORMATION**

A. Within 30 days after the conclusion of the case filed by the undersigned Plaintiffs' attorneys against the producing defendant, with the exceptions set forth below, the undersigned attorneys shall either return all the Confidential Discovery Material and copies thereof to the Producing Party at a location selected by the Producing Party and at the Receiving Party's



attorneys' expense, or produce an certification of compliance executed by the undersigned Receiving Party's attorneys indicating that all of the documents from the Producing Party and all copies thereof have been destroyed or will be destroyed within a reasonable time.

Counsel for the Receiving Party may retain their privileged communications, work product, and Acknowledgements pursuant to this Protective Order, materials required to be retained by applicable law, and all Confidential Discovery Material filed with the Court even though they contain discovery materials produced by the Producing Party, but such retained, privileged communications and work product shall remain subject to the terms of this Protective Order. Counsel for the Receiving Party shall also not be required to return or destroy any pretrial or trial records as are regularly maintained by that counsel in the ordinary course of business, which includes: (i) one full set of copies of all pleadings, affidavits, declarations, briefs, memoranda, expert reports, exhibits and other papers filed in this action; and (ii) one set of transcripts of all testimony taken at any depositions, hearings or trial with exhibits used therein. Any such materials that are not returned or destroyed shall remain subject to this Order, and the Court shall retain jurisdiction to ensure that the terms hereof are not violated.

## **12. MISCELLANEOUS PROVISIONS**

A. Nothing in this Order shall prevent any party or other person from seeking modification of this Order or from objecting to a confidentiality designation or redaction that it believes to be otherwise improper.

B. Nothing in this Order shall prevent a Party from any use of its own documents and information.

C. Nothing shall prevent disclosure beyond that limited by this Order if the Producing Party consents in writing to such disclosure.

D. This Protective Order remains in full force and effect and governs the use of

Confidential documents and information until amended or superseded by express order of the Court and shall survive and remain in effect after the conclusion of this litigation.

Dated: New York, New York  
October 1, 2014

Respectfully Submitted,

/s/ Andres Alonso

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SO ORDERED, this \_\_\_\_\_ day of  
\_\_\_\_\_, 2014.

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I further agree to return all copies of any Confidential Discovery Material or any document or thing containing Confidential Discovery Material I have received to counsel who

provided them to me, or to destroy such materials, upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Confidential Discovery Material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the Western District of New York, for the purposes of any proceedings relating to enforcement of the Order. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: \_\_\_\_\_

By: \_\_\_\_\_